JUL - 3 2000

K001148

X. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 Date Prepared

March 28, 2000

2.0 Submitter (Contact)

Dave Timlin, Manager Regulatory Affairs
Medtronic Xomed
Jacksonville, FL 32216
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3.0 Device Name

Proprietary Name: Xomed MeroGel™ Nasal Dressing and Sinus Stent

Common Name(s):

Ear, Nose and Throat Synthetic Polymer Material
Non-Woven Surgical Packing
Non-Woven Wound Dressing

Classification Name: Ear, Nose and Throat Synthetic Polymer Material

4.0 Device Classification

Ear, nose, and throat synthetic polymer material ProCode KHJ
Class II; 21 CFR 874.3620

5.0 Device Description

Medtronic Xomed MeroGel™ Otologic Pack is a biomaterial composed of HYAFF®, an ester of hyaluronic acid, a natural occurring constituent of the extracellular matrix. The material may be compressed and shaped by the surgeon according to the individual patient's needs for use as a space-occupying implant material. MeroGel™ Otologic Pack is offered in two sizes, a 1 cm x 5 cm size and a 4 cm x 4 cm, for the convenience of the surgeon, depending on the quantity needed for the specific procedure being performed. Due to its absorption properties, MeroGel™ may be used to help control minimal bleeding. In contact with body fluids, it changes into viscous and transparent gel, conforming to mucosal surfaces and eventually dissolves.

6.0 Intended Use

MeroGel™ Otologic Pack is a space occupying dressing and/or stent intended to separate mucosal surfaces, help control minimal bleeding and act as an adjunct to aid in the natural healing process. The device is indicated for use in the middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty, and stapes and mastoid surgery.

7.0 Substantial Equivalence

Medtronic Xomed markets both MeroGel™ Nasal Dressing and Sinus Stent and EpiFilm™ Otologic Lamina which together serve as the predicate devices for MeroGel™ Otologic Pack. MeroGel™ Nasal Dressing and Sinus Stent is made from the same MeroGel™ material which comprises the subject device, MeroGel™ Otologic Pack. EpiFilm™ Otologic Lamina is intended for use as an implant material to aid in surgical repairs and as an aid in the natural healing process in various otologic procedures. The subject device is substantially equivalent to MeroGel™ Nasal Dressing and Sinus Stent with respect to physical characteristics and the intended use of the devices. MeroGel™ Otologic Pack is substantially equivalent to EpiFilm™ Otologic Lamina with regards to the indicated use of the device. Both predicate devices are benzyl esters of hyaluronic acid made by the identical manufacturing processes. The subject and predicate devices are made from materials which have demonstrated satisfactory biocompatibility, are highly absorbent for collecting postop fluids, and are sterile single use.

In conclusion, Medtronic Xomed MeroGel™ Otologic Pack has the same indicated use as the predicate device EpiFilm™ and is comprised of the same material and has the same intended use as the predicate device MeroGel™ Nasal Dressing and Sinus Stent. The material has been shown as biocompatible, as based on the data in the submission raises no new issue of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2000

Mr. David Timlin
Director
Regulatory Affairs
Medtronic Xomed
6743 Southpoint Dr. N.
Jacksonville, Florida 32216-0980

Re: K001148
Trade Name: MeroGel ™ Otologic Pack
Regulatory Class: II
CFR: 874.3620
Product Code: 77KHJ
Dated: June 15, 2000
Received: June 16, 2000

Dear Mr. Timlin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations .

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Revised 6/15/00

Intended Use Statement

510(k) Number (if known): K001148

Device Name: MeroGel™ Otologic Pack
Indications for Use:

MeroGel™ Otologic Pack is a space occupying dressing and/or stent intended to separate mucosal surfaces, help control minimal bleeding and act as an adjunct to aid in the natural healing process. The device is indicated for use in the middle ear and external ear canal following canalplasty, myringoplasty, tympanoplasty, and stapes and mastoid surgery.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001148

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